

A³ (cont.)
7. (amended) The fusion device of claim 1, wherein:

said flat side walls terminate near said first end; and

said cylindrical portions and said threads are interrupted by said side walls and are circumferentially continuous thereafter [at] from said side walls to said first end.

12. (amended) A fusion device for facilitating arthrodesis in the disc space between adjacent vertebrae, comprising:

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an elongated body having a length, a first diameter at a first end and a larger second diameter at a second end opposite said first end, said first and second diameters sized to be greater than the space between the adjacent vertebrae, said body further defining a hollow interior sized to receive bone [graft] growth promoting material therein;

said body having an outer surface that is substantially continuously tapered from said first [diameter] end to said second [diameter] end with external threads defined [thereon] on said outer surface and extending [along] substantially entirely along said length of said body.

REMARKS

Reconsideration of the present application as amended is hereby requested. Deficiencies under 35 U.S.C. §112 were noted for claims 4, 6 and 7. Claim 4 has been amended to reflect that each of the opposed slots is larger than the totality of the number of openings in each opposite side wall. Claim 6 has been amended to indicate that the cylindrical portions define the "effective width", a term that is used to distinguish from the "width dimension" of the opposed slots. Claim 7 has

been amended to more clearly define the resumption of the cylindrical portions and threads after the side walls. In particular, the term "thereafter" has been clarified in relation to the side walls and the first end of the body.

Claims 1, 2 and 12 have been provisionally rejected under the double patenting proscription of 35 U.S.C. §101 in view of claims 1, 2 and 12 of Applicants' co-pending continuation-in-part application Serial No. 08/413,353. The claims of the present application differ from the asserted claims of the CIP by the definition in the present claims of a hollow interior sized to receive bone growth promoting material. No specific grounds for this rejection were asserted; however, it is presumed that this limiting language was regarded as inconsequential based upon a similar double patenting rejection in the co-pending '353 application.

It is respectfully asserted that a statutory double patenting rejection is improper in this case. The test for double patenting under 35 U.S.C. §101 is whether the same invention is being claimed twice. According to the M.P.E.P., one test for §101 double patenting is whether an embodiment of the invention falls within the scope of one claim and not the other. In the present case, claims 1, 2 and 12 all require a hollow interior. In the co-pending application, this limitation is omitted. Thus, a fusion device that is solid would fall within the scope of the co-pending application claims, but not within the scope of the present claims.

It is therefore believed that a statutory double patenting rejection of the present claims 1, 2 and 12 is improper. In the co-pending '353 application, an obviousness-type double patenting rejection was invoked. Applicants will submit an appropriate Terminal Disclaimer to overcome any such rejection in either the present application or the '353 application once the claims are deemed to be otherwise allowable.

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Each of the claims of the present application was rejected as obvious in view of the patent of Kuslich. In particular it was proposed that a combination Figures 14 and 1 of the Kuslich patent show every element of Applicants' claimed invention. Substantially the same rejection was issued in the co-pending '353 application. In the '353 application, Applicants filed an amendment that resulted in an indication of allowability of the claims of that application. The claims of the present application are more narrow than those allowed in the '353 application due to the definition the hollow interior to the fusion device. Moreover, the present claims were amended in conformance with the amendments in the co-pending application. Consequently, the arguments that were successful in the '353 application apply with equal force to overcome the rejection in view of the Kuslich patent in the present application.

To avoid redundancy, Applicants will only summarize the arguments set forth more fully in the response filed in the co-pending '353 application. With respect to claim 12 it was pointed out that the amended claim defines the body as having first and second diameters, with both diameters sized to be greater than the space between the adjacent vertebrae. Applicants' claimed invention is intended to restore the normal lordotic relationship or angle between adjacent vertebrae. In order to accomplish this purpose, the diameters at the opposite ends of the claimed implant are sufficient to span the intradiscal space and support the adjacent vertebrae. The device in the Kuslich '638 Patent cannot achieve this function. The Kuslich patent shows an embodiment having a bullet-shape design that is identified as assisting in insertion and advancement of the body 12' into the intervertebral space. The '638 Patent includes no

discussion of restoring normal lordotic angles between adjacent vertebrae, nor could the disclosed device accomplish this result. The '638 Patent neither discloses nor contemplates a body in which the diameters at the opposite ends are both larger than the intervertebral space, as set forth in amended claim 12.

Moreover, the body in the '638 Patent is not tapered substantially continuously from the first end to the second end, as now set forth in claim 12. Instead, the body 12' of the '638 Patent is tapered only at the leading end, as clearly reflected in FIG. 2A. The '638 Patent does not suggest or contemplate a threaded implant that is tapered along its entire length. Moreover, the Kuslich patent does not contemplate the externally threaded continuously tapered body of Applicants' claim 12. It was suggested that the threads of FIG. 1 of Kuslich could be combined with the non-threaded implant of FIGS. 14,15. Even if this combination is made, the resulting device still would not taper continuously from end-to-end, as required by claim 12. The implant of FIGS. 14, 15, also only taper at the leading ends of the devices to facilitate insertion. (Col. 8, lines 58-65). It is therefore believed that claim 12 is neither anticipated nor rendered obvious by the '638 Patent, and further that claim 12 is in condition for allowance.

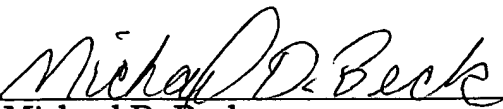
In making the rejection of claim 1, it was theorized that a person of ordinary skill in the art would readily add the threads of the embodiment of FIG. 1 to the non-threaded "oval-shaped" embodiment of FIGS. 14,15. The device in the '638 Patent fails to disclose or contemplate all the elements of Applicants' claim 1. Claim 1 requires that the fusion device has a first diameter defined by the opposite cylindrical portions at one end. The Kuslich device is "oval-shaped" (col. 8, l. 43) and does not have a first diameter defined by both cylindrical portions.

Instead, the cylindrical portions in the Kuslich device each define their own independent diameters, which of course results in the oval shape, rather than the cylindrical shape of the present claimed implant.

This oval shape of the '638 Patent device is fatal to the addition of threads as proposed in this Action. It cannot be disputed that an oval device cannot be threaded into the corresponding oval opening generated according to the Kuslich method as described at col. 9, lines 13-18. On the other hand, although no such suggestion is made in Kuslich, the oval implant could be threaded into a single bore; however, the diameter of this bore would necessarily be larger than the diameter of the two cylindrical portions of the Kuslich implant of FIGS. 14,15. Furthermore, adding threads to the Kuslich oval implant would render the device incapable of being implanted. In accordance with the suggested combination, the oval cylindrical portions 128 would carry threads while the flat portions 124, 126 would be non-threaded. As this hypothetical device is inserted into a prepared bore, the vertebral bodies would rise and fall as the flat portions alternately rotate against the vertebrae. Such a device could not be inserted in a controlled manner. The '638 Patent does not contemplate adding threads to the oval embodiment for these clear reasons. Since the '638 Patent non-threaded oval device cannot be provided with threads, this reference cannot be said to render Applicants' claims obvious. This claim, along with its dependent claims 2-11, are therefore believed to be allowable.

In view of the foregoing arguments and amendments it is believed that the present application is in condition for allowance. As discussed above, claims 1-14 are definite under Section 112 and are neither anticipated nor rendered obvious by the Kuslich '638 Patent. Consequently, action toward a Notice of Allowance is hereby solicited.

Respectfully submitted,

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